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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,650	07/07/2003	Yong Hua Zhu	LOMAU.122C1	7638
20995	7590	06/20/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			TRUONG, LINH T	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3761	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/614,650

Applicant(s)

ZHU ET AL.

Examiner

Linh Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-6 and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-15 and 25-27 is/are allowed.
- 6) ☒ Claim(s) 2-6, 8-10, 16 and 21-24 is/are rejected.
- 7) ☒ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/9/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Allowable Subject Matter***

The indicated allowability of claims 10 and 16 are withdrawn in view of the newly discovered reference(s) to Ernst et al., EP 0 482 350 and Hasson '4,744,363, respectively. Rejections based on the newly cited reference(s) follow.

### ***Response to Amendment***

The amendment filed 7 July 2003 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claims 21-24.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe "first and second lumens (that) do not communicate with one another" nor does it describe where "the first and second lumens are arranged generally side by side."

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerslag '5,759,194 (IDS) in view of Janzen et al. EP 0 482 350.

For claims 2-6 and 10, Hammerschlag teaches a tissue closure device comprising: an elongate body with a first portion 80 and a second portion 270 having a lumen, each portions having a distal end; the second portion 270 cannot be moved distally relative to the first portion distal end beyond the minimum distance and is arranged concentrically and rigidly around the first portion 80, a patch 88 releasably connected to the distal end of the first portion, wherein the second portion lumen distal opening is spaced from the patch. The two portions extend generally parallel to a longitudinal axis of the elongate body and the first portion has a lumen having a first

lumen opening through the distal end with the patch covering at least a portion of the distal opening (fig. 11 and col. 14, lines 43-57).

The difference is the first lumen is adapted to slidably receive a release rod. Release rods/push rods are well known in the tissue closure art for holding wound closure members in place as taught by Janzen et al. Janzen et al. teach a device for inserting hemostatic material for sealing puncture wounds; the device has a piston 49 (release rod) that pushes and holds the plug 57 (patch) in place until a self-sustaining seal has been achieved (col.7, lines 5-31). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the invention of Hammerschlag with the piston/release rod of Janzen et al. to hold the patch in place until a self-sustaining seal has been achieved.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerslag '5,759,194 (IDS) in view of Janzen et al. EP 0 482 350 and in further view of Wilk et al. '5,236,455.

For claims 8-9, Hammerschlag and Janzen et al. do not teach that the first lumen is connectable to a source of vacuum. A vacuum source is well known in the art of tissue closure for holding a patch in place as taught by Wilk et al.. Wilk et al. teaches a patch applicator with a lumen 52 connected to a source or vacuum 58 for holding patch 50 temporarily in place before application to a ruptured membrane (fig. 4, col. 4, lines 43-56). Therefore, it is obvious to one with ordinary skill in the art at the time the

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invention was made to provide the invention of Hammerschlag and Janzen et al. with a vacuum source for temporarily holding a patch in place prior to its application.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerslag '5,759,194 (IDS) in view of Janzen et al. EP 0 482 350 and in further view of Hasson '4,744,363.

For claim 16, both Hammerschlag and Janzen do not teach a tissue closure device with an organ stabilizer. Organ stabilizers are well known in the surgery art for holding organs in place for easier access to the site being treated as taught by Hasson. Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the invention of Hammerschlag and Janzen et al. with a movable organ stabilizer in order to hold an organ and/or tissue in place for easier access to a wound site.

***Allowable Subject Matter***

Claims 11-15 and 25-27 are allowed.

Claims 17-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 571-272-4938. The examiner can normally be reached Mondays to Fridays from 10am to 4pm.

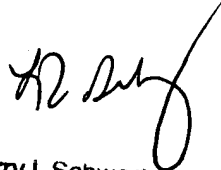
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on 571-272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Linh Truong

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*L.T.*

  
Larry I. Schwartz  
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Group 3700